Brief Summary of the Circulatory System Devices Panel Meeting – May 7, 2014

Introduction:

The Circulatory System Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on May 7, 2014, to discuss and make recommendations regarding the classification of membrane lung for long-term pulmonary support systems, one of the remaining pre-amendment Class III devices regulated under the 510(k) pathway. A membrane lung for long-term pulmonary support refers to the oxygenator component of an extracorporeal circuit used during long-term procedures, commonly referred to as extracorporeal membrane oxygenation (ECMO). An ECMO procedure provides assisted extracorporeal circulation and physiologic gas exchange of a patient's blood when an acute (reversible) condition prevents the patient's own body from providing the physiologic gas exchange needed to sustain life. The circuit is comprised of multiple device types, including, but not limited to, an oxygenator, blood pump, cannulae, heat exchanger, tubing, filters, monitors/detectors, and other accessories; the circuit components and configuration (e.g., arteriovenous, veno-venous) may differ based on the needs of the individual patient or the condition being treated. ECMO is currently used for patients with respiratory, cardiorespiratory, and most recently cardiac failure, unresponsive to optimal ventilation and/or pharmacologic management.

Today's discussions focused on the adult patient population. The pediatric patient population was already discussed at a Panel meeting that took place on September 12, 2013 where reclassification was recommended for conditions where an acute (reversible) condition prevents the patient's own body from providing the physiologic gas exchange needed to sustain life in conditions where imminent death is threatened by respiratory failure (e.g., meconium aspiration, congenital diaphragmatic hernia, pulmonary hypertension) in neonates and infants, or cardiorespiratory failure (resulting in the inability to separate from cardiopulmonary bypass following cardiac surgery) in all pediatric patients.

Panel Deliberations/FDA Questions:

***Important Panel deliberation topics*:**

- *Broadness of the categories (i.e., "pulmonary" and "cardiopulmonary") may open the door for marketing the device inappropriately.*
- *Cardiopulmonary vs cardiac indications. Cardiac indications fall into the VAD category and should not be included in the ECMO indications.*
- *How classification will/may affect clinical use of ECMO - practice of medicine vs. cleared/approved labeling for the device was discussed*
- *How classification may affect ability to obtain clinical data for ECMO – if Class II, we may get more clinical data and more FDA over-site. If Class III, it may remain in the practice of medicine category with current unknowns regarding safety and effectiveness.*

- *How classification may encourage/stifle innovative technology in ECMO – class II was felt to encourage innovative technology*
- *How classification will affect FDA over-site on the pre-market side.*
- *How individual components will be evaluated/reviewed in the context of an entire circuit being defined for the new regulation – a discussion ensued regarding the fact that each component will have its own set of unique set of special controls (if Class II) or PMA requirements (if Class III)*
- *Effectiveness is not strong for any of the indications discussed.*
- *Risks to health vs adverse events discussions were held and appeared to be understood by the Panel.*

FDA Questions

1. **Risks to health**
   - Panel agreed that the list presented by FDA is comprehensive

2. **Evaluation of Safety and Effectiveness**

2a Does available scientific evidence support safety and effectiveness for adult long-term pulmonary support:
   - Globally, no; but there may be some indications that could be reclassified, e.g., H1N1, ARDS
   - Suggested new wording to capture broad pulmonary adult indications for Class II – "**acute, hypoxic, reversible respiratory failure**".

2b Do benefits outweigh risks for adult pulmonary ECMO?
   - Yes, but only with new language for indication identified in 2a

2c Does available scientific evidence support safety and effectiveness for adult cardiopulmonary ECMO?
   - Panel agrees that ECMO is safe and effective for long-term cardiopulmonary support.
   - Specific wording for cardiopulmonary indication was suggested as "**long-term support of cardiopulmonary failure due to acute catastrophic cardiogenic shock**."

2d Do benefits outweigh risks for adult cardiopulmonary ECMO
   - Panel agrees that benefits outweigh risks for long-term cardiopulmonary support

3. **Special Controls**

   - Panel is comfortable with listed special controls, appropriate, comprehensive – for newly defined pulmonary and cardiopulmonary indications identified in question 2 above.
   - Discussion ensued regarding use of post-market surveillance as a special control – some agree it is a good idea and some think it impractical and with too many limitations to give us valuable data - especially in the context of a special control.

4. **Recommended classification**

4a Is ECMO for adult pulmonary support life supporting:

- Panel believes that extracorporeal circuit and accessories for long-term pulmonary support **are life-supporting**

4b Is ECMO for adult cardiopulmonary support life supporting:

- Panel believes that extracorporeal circuit and accessories for long-term cardiopulmonary pulmonary support **are life-supporting**

4c What classification do you recommend for long-term pulmonary support for the adult patient population [as identified in 2a above]:

- Most Panel members agreed that **Class II was sufficient for this narrower definition of pulmonary support (as identified in 2a above**), some with the stipulation of the collection of registry data as a special control; but several panel members stated that they believe that the evidence does not support down-classification to Class II

4d What classification do you recommend for long-term pulmonary support for the adult patient population [as identified in 2c above]:

- All panel members agreed that cardiopulmonary indications, **as defined in 2c above, can be reclassified to Class II** with the special controls listed.

4e Reasons for Class II recommendation:

- More regulatory control if Class II to obtain data in an application as opposed to practice of medicine where the docs have very little information about the intended use.
- Information would need to be provided in an application to address the risks to health (i.e., special controls)
- Concern that efficacy data is weak for both indications: Cardiopulmonary indication has gotten a "pass" due to potential death leading to the need for the device; pulmonary it is more difficult to determine when device is useful
- Concerns- Further innovation with engineering design needed so class II might encourage innovation

Summary:

Class II

- Extracorporeal circuit and accessories for long-term support for acute hypoxic [reversible] respiratory failure in adults.
- Extracorporeal circuit and accessories for long-term support of cardiopulmonary failure due to acute catastrophic cardiogenic shock (e.g., failure-to-wean and ECMO supported CPR [E-CPR]), in adults.

Contact: Jamie Waterhouse, Designated Federal Officer,
(301) 796- 3063 Jamie.Waterhouse@fda.hhs.gov
Transcripts may be purchased from: (written requests only)
Free State Reporting, Inc. 1378
Cape St. Claire Road Annapolis, MD 21409
410-974-0947 or 800-231-8973 Ext. 103
410-974-0297 fax
Or
Food and Drug Administration
Freedom of Information Staff (FOI)
5600 Fishers Lane, HFI-35
Rockville, MD 20851
(301) 827-6500 (voice), (301) 443-1726